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FARM ANIMAL CLONING: THE CURRENT LEGISLATIVE FRAMEWORK

A review describing the existing law, and its practical application within and beyond the EU

Christian Gamborg, Jennifer Gunning & Mette Hartlev

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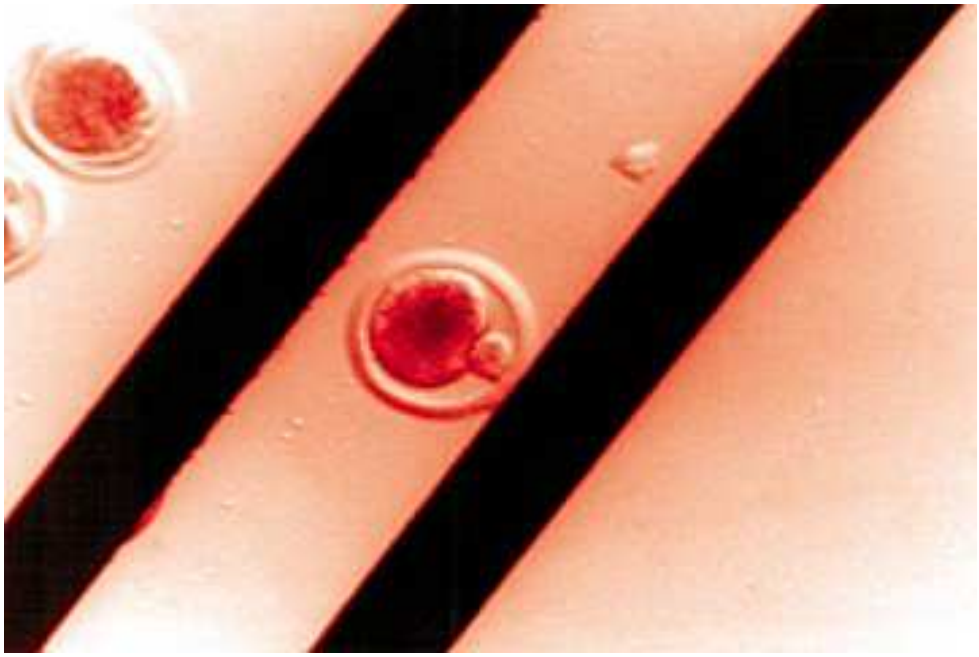

Report from the project Cloning in Public
A specific support action within the 6th framework programme, priority 5: Food quality and safety

Coordinator: Danish Centre for Bioethics and Risk Assessment (CeBRA)
http://www.bioethics.kvl.dk

0. Executive summary

This report reviews the state of the existing legislative framework and the actual practice of animal biotechnology regulation within and outside the European Union (EU). Unless stated otherwise, "farm animal cloning" refers in the report to the cloning of farm animal species such as cattle, sheep and pigs by somatic cell nuclear transfer (as opposed to embryo splitting) **'**Applications of this may be pursued in biomedicine as well as agriculture.

Unlike the genetic modification of animals, cloning is not directly regulated at EU level. The only piece of EU legislation applying to cloned animals for *food* production is EU Regulation No 258/97 on novel foods and novel food ingredients – provided food derived from cloned animals is considered to fulfil the legal criteria stated in the Regulation. It must be noted, though, that food derived from cloned animals has not been placed on any European or other market. GM directive 2001/18/EC needs to be evaluated for its relevance to animal cloning. Likewise, zootechnical and other animal health and welfare legislation should be checked for the potential existence of a legal vacuum (e.g. in relation to sperm transfer).

The EU has adopted a scientific and risk-based approach to food. According to the Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, all food needs to be traced. However, this is by no means a given order of events, as there might be other ethical concerns about products derived from cloned animals and the food chain which cannot be assessed from a hazard perspective.

A number of Member States, though not all, perform animal cloning for research purposes. However, as of yet no products from cloned animals or their offspring are on the market. Most EU Member States and European countries have not passed specific legislation on animal cloning. A limited number of countries are currently contemplating such legislation. A few countries – Norway (a non-Member State) in 2004 and Denmark in 2005 – have actually passed specific legislation on animal cloning.

According to the Opinion of the Group of Advisers on Ethical Implications of Biotechnology to the European Commission – which is not legally binding – cloning of farm animal species for research is acceptable only if it is carried out under conditions which avoid or minimise animal suffering. The reason for permitting animal cloning research is, according to the Group, that it is likely to add to our knowledge and understanding of biological processes. In the agricultural context, animal cloning was seen as a way to improve the selection of animals having specific qualities, either innate or acquired by genetic modification.

Major, research-heavy countries like the US, Canada, Australia, China and Japan have – like their European counterparts – no specific legislation on animal cloning. Japan is reported to have significant farm animal cloning activities; likewise South Korea and China. In some of these countries it seems likely that cloning and the sale of cloning-derived products in home markets will be allowed. This will present the WTO with a challenge. Most likely, efforts from the EU countries to prevent these products from entering the European markets with the stated aim of protecting consumer interests will probably depend on the WTO interpretation of the precautionary principle, and on what it sees as a "legitimate concern". Normally, health risks and risks to the environment are seen as legitimate interests. These can be invoked, for

example, to prevent or regulate the movement of living animals and animal products across national borders.

Cloning technology may have commercial significance, so patenting (i.e. the legal protection of so-called biological inventions) is surveyed here. There are uncertainties about patenting of the processes of animal cloning, cloned animals, their offspring and products derived from cloned animals. The Biotechnology directive (98/44/EC), while stating that human cloning cannot be the subject matter of a patent, is silent on animal cloning. A non-exhaustive list of unpatentable processes exists, and this list may suggest that animal cloning can be patented. However, since the list can be supplemented, it remains possible that patenting of cloned animals will be considered contrary to public order and morality. Moreover, the question remains whether the invention criterion is satisfied when it comes to cloned animals.

At the end of the report some of the main questions and key issues it identifies about the regulation of farm animal cloning are highlighted.

Contents

1. Introduction

This report is the second deliverable from the project "CLONING IN PUBLIC; a specific support action within the sixth framework programme, Priority 5, Food quality and safety" (Contract no. 514059).

The main objectives of CLONING IN PUBLIC are: (a) to develop recommendations on the preparation of European regulation of, and guidelines covering, research on farm animal cloning and its subsequent applications (e.g. in genetically modified animals for bio-reactors); and (b) to stimulate informed public debate across Europe on these issues involving key stakeholders, university students and members of the public. These two aims are of equal importance. They are also interrelated, because if regulations and guidelines are to serve their purpose, they must take public concerns into account. In addition, stimulating, informing and reporting public debate is part of the more general, long-term aim of improving communication between science, civil society and European authorities at different levels, and hence facilitating discussion of European public affairs connected with science and technology.

The report reviews the state of the existing regulatory framework pertaining to farm animal cloning and the actual practice of animal biotechnology regulation to date, both nationally and at EU level. The main regulatory traditions and practices in Europe will be characterised and compared with those in other countries/regions (e.g. the US). Moreover, the report maps the European legal framework by describing existing national and supra-national regulation and other legal frameworks with an impact on the research and use of farm animal cloning both within the EU and in a number of significant countries outside the EU (in particular the US, Australia and a number of Asian countries including Japan). Here relevant international conventions, EC directives, protocols and resolutions will be examined, along with regulation following World Trade Organisation (WTO) and World Organisation for Animal Health (OIE) agreements. Moreover, harmonising measures affecting EU Member States will be discussed. International regulation may set the scene for, or complement, national regulation. Different examples of national regulation within Europe will be presented to show the different directions taken in individual countries and to illustrate different approaches to the regulation of cloning and other forms of animal biotechnology. Cloning may have commercial significance, so the issue of patenting (i.e. the legal protection of so-called biological inventions) will be surveyed.

What is cloning?

Within the project CLONING IN PUBLIC the concept of farm animal cloning is defined as asexual reproduction, or more precisely the production of individuals with (virtually (NRC, 2002 p. 18, Poland & Bishop, 2002)) identical genetic materia by asexual reproduction.

Since the production of the Dorset Eve Dolly in 1997 by Wilmut et al. (Wilmut et al. 1997)) the focus of research has beer on Somatic Cell Nuclear Transfer (SCNT), which is therefore also the kind of cloning that the project CLONING IN PUBLIC focuses on. This does not deny the fact that there are other ways of cloning farm animals, but implies that fo most of the applications of cloning discussed today cloning by SCNT is the selected technology.

Below is a short introduction to the three main ways of producing a cloned farm animal (producing a farm animal with asexual reproduction). For further explanations of the technologies involved we direct attention to the report The Science and Technology of Farm Animal Cloning. A review of the state of the art of the science, the technology,the problems and the possibilities published by The Danish Centre for Bioethics and Risk Assessment in 2005 in connection with the projec CLONING IN PUBLIC (Danish Centre for Bioethics and Risk Assessment 2005)

Embryo Splitting
Successful experiments with cloning by splitting two-cells embryos of sea urchins were reported already in 1891 by Hans Driesh. It was, however, not until 1979 that Steen Willadsen successfully cloned domestic animals by splitting embryos with the purpose of rapid multiplication of valuable individuals. However, following initial enthusiasm, the procedure failed to become as efficient as expected: technical difficulties, compromised pregnancy rates and the simple mathematical limits of the procedure had not been fully appreciated. Even if the technical difficulties had been resolved and the pregnancy rates improved, it would have remained the case that an embryo can only be split 1-2 times and thus can create at most 2-4 genetically identical siblings through artificial splitting.

Embryonic Cell Cloning
Another approach to asexual reproduction is embryonic cell cloning. Experiments on this technology has also been going on since the 1890´ies, but it was first in 1986 that Steen Willadsen could present the first cloned farm animals using the technology. To perform embryonic cell cloning the cells from an early embryo are separated and individually transferred into oocytes (egg cells). They will then develop into a new embryo. By this method a theoretical maximum of 32 cloned individuals can be created on the basis of one 32 cell embryo – all carrying the genes from the first embryo.

Some animal breeding companies regarded it as a potentially useful way of rapidly multiplying animals with valuable genetic traits, but the efficiency of the technique remained stubbornly low. (The theoretical maximum is 32 transferable embryos from a single 32-cell donor embryo. This was never reached.) As it turned out, income generated by the advance did not cover the costs of the laboratory and embryo transfer work. Eventually, support for research in this field dramatically decreased in the early 1990s, and except for a few laboratories embryologists throughout the world have focused on other subjects.

Although embryo splitting and embryonic cell cloning differs in many ways they share the important premise that only cell from embryos can be cloned. This has the practical importance only genotypic information (information about the genes present in the individual animal) about the animal that is cloned can be known. For obvious reasons there is no way to know how these genes will express themselves in the born animal (phenotypic information) although predictions can be made on the basis of information about donors of oocytes and sperm to the original embryos.

Somatic Cell Nuclear Transfer
The production of the Dorset ewe Dolly in 1997 showed that it was possible to create clones of adult animals too, thus having a much better knowledge of the phenotypic traits that was deemed desirable to copy through cloning. The method of somatic cell nuclear transfer (SCNT) entails taking a somatic cell from the animal that one desires to clone (in theory any cell from an individual that carries the full genome of that individual can be used). This cell is then transferred to an oocyte (egg cell) that has been emptied of its own DNA. The cell is hereafter stimulated to grow and will (theoretically) develop as a normally fertilized egg. It can then be transferred to a surrogate mother animal where it can continue its development until birth.

It should be noted that both embryonic cell cloning and somatic cell nuclear transfer does not produce an exact genetic replica of the donor animal. Even though the oocytes used when producing the clones are emptied of the genetic material present in the cell nuclei prior to the insertion of either the embryonic or somatic cell carrying the genetic information from the animal one desires to clone, one cannot avoid introducing additional genes into the cloned animals. This is caused by the fact that DNA is not only present in the nucleus of the oocytes, but also in the mitochondrias. This mitochondrial DNA, although only responsible for a very small part of the genes in the cloned animals, prevents the cloned animal from being an exact genetic copy of the donor animal. The importance of the mitochondrial DNA both for the problems with the technology and for future applications are so far unclear.

What is genetic modification

The cloning of farm animals through the use of somatic cell nuclear transfer allows for the production of an almost exact genetic copy of an animal. The technology can be used on animals whose genome is the result of normal sexual reproduction or reproduction that has been "helped" long by various technologies such as embryo transfer, artificial insemination, in vitro insemination etc. But the technology can also be used to produce clones of animals who have been genetically modified through various kinds of gene technology.

Genetic modification can take place in a number of ways, including inserting artificial genes or genes from other species into cells or an embryo in the early stages of development. The change can also take the form of a "turning off" of a certain gene or the insertion of additional copies of an already existing gene. The different ways that genetic modification can take place are closely described in?

Genetic modification is a way to produce animals with phenotypic traits that would usually not be possible through conventional breeding methods. The animals produced can potentially be used within basic research, medical research, the biomedical industry, agriculture and the pet industry. Potentially cloning combined with GM could produce large numbers of animals with desirable phenotypes that it would not otherwise be possible to produce. However, due both to the low efficiency rates of cloning and the possibility of transferring the desired genes into a given population of animals through a few founding animals and conventional breeding strategies, cloning has, so far, only played a limited role within the production of genetically modified animals.

The possible applications of GM and cloning on farm animals are closely examined in *The Science and Technology o Farm Animal Cloning. A review of the state of the art of the science, the technology, the problems and the possibilities* published by The Danish Centre for Bioethics and Risk Assessment in 2005 in connection with the project CLONING IN PUBLIC.

In this report, the term "cloning" refers here to reproductive biology in the sense of *asexual reproduction*, or more precisely the production of individuals with virtually identical genetic material by asexual reproduction. In recent debates, interest has centred on cloning by means of somatic cell nuclear transfer (SCNT).[1] The term "farm animal" refers to farm animal species such as ruminants (e.g. cows, sheep), pigs and poultry (chicken, turkey). The term does *not* imply that an animal is kept or used in an agricultural setting or for agricultural purposes. Thus, the potential application of a cloned farm animal species may be in medicine (see the first technical report from the CLONING IN PUBLIC project, 2005). The report does not cover legislation pertaining only to genetically modified animals. However, where legislation may reasonably be suspected of covering cloning *as well as* genetic modification, regulatory aspects of genetic modification will be indirectly covered.

This report forms the basis of a second *legal* report containing an assessment of the legislative framework currently in place. The second legal report will aim to identify possible adjustments to the extent and type (direct or indirect) of currently operating legal instruments. It will take into account both scientific and commercial developments as well as public and stakeholder opinion.

CLONING IN PUBLIC reports on the scientific, legal and ethical aspects of farm animal cloning are publicly available. All project reports, as well a list of project deliverables, presentations, work plans and workshops are available at the project website: http://www.bioethics.kvl.dk or http://www.sl.kvl.dk/cloninginpublic/

[1] For further explanation, see the CLONING IN PUBLIC report "The science and technology of farm animal cloning" available at http://www.sl.kvl.dk/cloninginpublic/.

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The picture on the front page of this report was downloaded from the Roslin Institute Image Library: http://www.roslin.ac.uk/imagelibrary/.

2. Regulatory mechanisms and guiding principles for regulation

2.1 Regulatory mechanisms

The ordering of conduct in society is generally regulated by instruments, legal or otherwise, which are established to uphold moral standards, to promote the wellbeing and safety of citizens and to protect individuals and the environment. Regulatory mechanisms can come into play at a number of different levels, from international and global to national and local, and from statutory instruments with mandatory requirements and penalties to guidelines with no legal force. But even instruments having no legal force still have legal value.[2]

International regulatory mechanisms

International legal instruments usually take the form of treaties or conventions which form agreements between a number of independent states which sign and then ratify them. Usually a minimum number of ratifications is required before the instrument becomes legally binding. Treaties and conventions may also have subsidiary agreements called protocols which also require signature and ratification to become enforceable. These regulatory mechanisms are only legally binding on those nations which ratify them. They may therefore be weakened by the fact that a powerful nation, such as the US, does not sign or ratify them. Where international consensus is not possible, an agreement may take the form of a declaration, recommendation or resolution that is not legally binding. This has happened recently in the United Nations (UN) in connection with human cloning. Here, some nations wished to ban all forms of cloning, but others wished to pursue research on therapeutic cloning.

The UN plays a central role in developing worldwide international law by means of conventions, treaties and standards. Established in 1945 by 50 Member States, the UN now has 191 Member States and has produced some 500 multilateral agreements.

Worldwide trade agreements are handled by the WTO, which deals with the rules of trade between nations. The WTO was established in 1995 as the successor to the General Agreement on Tariffs and Trade (GATT). WTO agreements are negotiated and signed by the majority of the world's trading nations, and are ratified by their parliaments. They provide a legal underpinning for international trade and aim to remove trade conflicts. The WTO has thus become the arbiter of trade disputes between countries. The Agriculture Agreement sets out rules on agricultural trade between countries and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) introduces international intellectual property rules. Both agreements may impinge on animal cloning – for instance, if a country places an embargo on imports of products derived from cloned animals. Such an embargo will in general only be acceptable under WTO rules if there is a legitimate public health interest (e.g. because the product is unsafe in some way).

[2] In international law the term "soft law" is often used to distinguish legal instruments that have no formal legal force from binding legal instruments. However, even though "soft law" has no formal legal force it is still "law", which means that it is part of the normative framework. The European Court of Justice sometimes refers to and interprets EU "soft law".

In Europe, the Council of Europe plays a similar political role. Established in 1949, it now comprises 46 Member States, including 21 countries from Central and Eastern Europe. The Council has issued 196 legally binding European treaties or conventions. Many of these can also be signed by non-Member States. The decision-making body of the Council of Europe is the Committee of Ministers, on which the Foreign Ministers of all Member States sit. The Committee of Ministers may make recommendations to governments on issues such as legal matters, health, education, culture and sport, but these recommendations are not legally binding. The Council of Europe also has a non-elected Parliamentary Assembly. This enters into dialogue with the Committee of Ministers by means of recommendations, resolutions and opinions following advice from one of its advisory committees. Discussion of an issue may therefore start at committee level and culminate in the adoption of a convention on the basis of a two-thirds majority in the Committee of Ministers. Similar bodies exist in other parts of the world.

The European Union was founded to enhance political, economic and social cooperation between its (now 25) Member States. Decision-making and regulation are shared between three institutions: the Council and the Parliament (which together pass new laws), and the Commission (which proposes them). Founded by Treaty, the EU issues directives and Regulations which are legally binding on Member States. In the case of directives, Member States are expected to transpose these into national legislation, but the speed and level of detail at which this is done can vary between states. Under the Treaty, the European Commission has the 'right of initiative' which means that it is responsible for drawing up new proposals for legislation to put before the Parliament and Council. Before doing this, the Commission must be aware of new situations and problems developing in Europe, and it must consider whether EU legislation is the best way to deal with them. Action will be taken at EU level only if the Commission believes that a problem cannot be solved more efficiently by national, regional or local action – this is required by the so-called 'principle of subsidiarity'. In deciding whether or not to propose legislation the Commission will consult both within the Member States and among its own groups of experts and committees. The advisory committees of the Commission may issue opinions on issues and, whilst these opinions may be a prelude to legislation, they are not legally binding.

National regulatory mechanisms

Statutes or laws are the most binding form of regulatory mechanism at national level. These set out permitted or prohibited activities, with penalties for non-compliance, or require action which promotes consumer protection and consumer choice through, for instance, product labelling. [3] Legislation may also result in the establishment of statutory regulatory bodies or agencies which monitor compliance with the law, issue licences for approved activities and develop codes of practice which are legally binding. Before enacting legislation in controversial areas governments will usually undertake some form of consultation or enquiry. This may involve consulting a national ethics committee, setting up a specific advisory body or committee of enquiry, or circulating draft legislation for public comment.

As well as issuing legally binding administrative regulation, ministries may issue guidelines or codes which are not legally binding. For instance, the UK Agriculture (Miscellaneous Provisions) Act 1968 allows ministers to publish codes of recommendations for the welfare of

[3] Members States carry out controls on food legislation. As a Commission service, the Food and Veterinary Office (FVO) will audit national control on food legislation. See also chapter 6.2 in this report

livestock – these are usually referred to as the "welfare codes". The purpose of the codes is to encourage farmers to adopt the highest standards of husbandry. Although it is not a legal requirement to follow a code, failure to do so may be used as evidence when someone is being prosecuted for causing unnecessary pain or distress to livestock. Prosecutions in this type of case may be brought by an animal protection organisation such as the Royal Society for the Protection of Animals, so that even NGOs can have a role to play. However, the standards are ultimately enforced by the courts.

Local or regional mechanisms
At a local and regional level, activities may be regulated by local agencies or, in the case of medicine and research, through institutional and/or regional ethics committees.

Other regulatory mechanisms
The conduct of individuals may be controlled by professional self-regulation through guidelines and codes of practice. Professional bodies may also have ethics committees. NGOs may also issue guidelines; these, too, are not legally binding but may be picked up by statutory regulators in drafting their own regulations.

Consumer interests and consumer protection can be met through labelling regulations. These can be mandatory, as in the case of the use of additives or GMOs in food, or voluntary, as in the case of 'farm assured' or 'fair trade' products.

2.2 Guiding principles for regulation

Before regulating an activity consideration needs to be given to its novelty and desirability. In fact, a number of questions need to be asked.

- Does the activity raise any new ethical issues? If the answer is yes, these issues need to be discussed both at the expert advisory and public level.

- Does the activity involve any risks? Risks, for example, to animal welfare, or to human or environmental safety, need to be identified and evaluated in risk assessments.

- Does the activity fall under any existing regulation? A view needs to be taken as to whether the activity would be controlled by any existing regulations, and whether such regulations might be amended to deal with the activity more specifically.

- Is specific regulation required to deal with this activity alone? It may be that existing regulations only deal with some aspects of the activity.

- What is the appropriate form of regulation?

It may be that the proposed activity is so morally reprehensible that it must be prohibited altogether. In this case it might be possible to agree upon an international legal instrument banning the activity worldwide. This is usually difficult. An attempt to draft a UN treaty banning all human cloning has failed. It may be that one aspect of the activity is considered morally reprehensible while other aspects are beneficial. In this case, although international legal instruments may still have a role to play, national legislation may be more appropriate.

In this way aspects of the activity may be allowed to continue in those countries where they are considered acceptable. Many countries have either introduced law, or signed protocols, banning human reproductive cloning. However, 'therapeutic cloning' continues to be allowed in a number of countries.

If a European country decides to prohibit both an activity *and* the import of any products resulting from that activity, it may find itself in conflict with EU legislation promoting the free flow of products within the EU. It might also find itself in conflict with international trade agreements.

It may be that the activity is morally acceptable to the majority but entails some risks. Regulation may then be introduced to address these risks, and to ensure standards are met. It may also be appropriate to set up advisory or regulatory bodies to ensure compliance.

Some sections of society may, nonetheless, object to the activity – and may wish, as a result, to avoid consuming products resulting from the activity. Protection of these consumer interests could be met by labelling regulations.

In the consultation period leading up to any statutory regulation it may be that, particularly in the field of biotechnological activity, professional bodies will wish to impose interim guidelines. In the case of animal cloning, the lead might be taken by a body such as the International Embryo Transfer Society. Alternatively, voluntary moratoria might be sought.

3. International legislation, other legal frameworks and actual regulatory practice

3.1 EU legislation

Current EU legislation, other legal frameworks and actual regulatory practice
There is currently no EU legislation specifically concerning animal cloning. However, this activity falls under a number directives and Regulations addressing other issues, such as animal welfare, intellectual property protection, the use of GMOs and product labelling. When it comes to possible food applications derived from cloned animals the area is harmonised through the Regulation 258/97/EC concerning new production processes which has impact on food and novel foods and novel food ingredients if the food applications full fill the criteria of novel food regulation **.** Concerning the Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, its relevance needs to be evaluated especially when using animal cloning as a tool for introducing transgenesis. It has been argued that by cloning (SCNT) the genetic material is not altered (by recombination) as stated in article 2 (2) of the Directive 2001/18/EC.[4]]

Currently national legislation on cloning has been introduced in Norway[5] and Denmark. The Opinion of the European Group on Ethics (EGE) on the *Ethical aspects of cloning techniques* of 28 May 1997[6] concludes that research on cloning farm animals is acceptable provided it is carried out with strict regard for animal welfare. Not only would such research be likely to add to knowledge and understanding of biological processes but it may also prove to be of medical, agricultural and economic benefit. The Group saw the potential uses of cloning animals being, in the field of medicine and medical research, to improve genetic and physiological knowledge to make models for human diseases, as a source of therapeutic molecules in milk and as a potential source or organs or tissue for xenotransplantation. In the agricultural context, animal cloning was seen as a way to improve the selection of animals having specific qualities, either innate or acquired by transgenesis. Also, because of the uncertainties of transgenesis, cloning was seen to be a method to reproduce animals of high performance and so reducing the number of transgenic animals needed leading to animal welfare and cost benefits. A cautionary note was raised in the context of agricultural improvement in that, if the level of the general herd is brought up to elite level, there could be a loss of genetic diversity. The EGE has also considered ethical aspects of the genetic modification of animals.[7] Since genetically modified animals may also be cloned, this Opinion may also be relevant in this context. The Group considered that genetic modification

[4] In article 2 (2) it is defined that genetically modified organism (GMO) means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does no occur naturally by mating and/or natural recombination.' Within the terms of this definition genetic modification occurs at least through the use of the techniques listed in Annex I A, part 1. There is inter alia techniques listed (2) involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation. The technique used SCNT falls within this description. For the two other techniques listed in the Annex it is mentioned that they apply for recombination or new combination of genetic material.
[5] Amendment of May 2004 to the Norwegian Act on gene technology (see Section 4.1)
[6] Opinion of the group of advisers on the ethical implications of biotechnology to the European Commission. *Ethical aspects of cloning techniques*, 28 May 1997
[7] Opinion of the group of advisers on the ethical implications of biotechnology to the European Commission. *Ethical aspects of genetic modification of animals*, 29 September 1992

would add to, rather than replace, existing techniques. It took the utility of genetic modification to lie in the construction of models of human disease, the provision of alternative sources of tissues and organs for xenotransplantation, and the improvement of farm animals. The Group offered the opinion that "genetic modification may contribute to human wellbeing and welfare, but is acceptable only when the aims are ethically justified and when it is carried out under ethical conditions". [8]

The risks of farm animal cloning activities include risks to human health, animal welfare, the environment, and biodiversity. As it has been stressed in the first technical report of the CLONING IN PUBLIC project, the state of knowledge about the different risks varies according to the potential area of application. For example, in relation to using cloned farm animal for *bio-reactor* purposes, especially the risk of introducing new diseases (zoonoses) into humans by using animals as medicine factories generates a serious need for these biological compounds to be thoroughly tested before commercialisation.

When it comes to a possible application with relation to *xenotransplantation*, the use of nonhuman primates as donors has largely been ruled out owing to problems with raising them, welfare problems affecting the animals (e.g. isolation of infants) and a suspected higher risk of transferring diseases from donor to human recipient. E.g. it has been shown that endogenous retroviruses can be produced by porcine cell lines and infect human cell lines. A porcine lymphotropic herpesvirus has been identified. The risks associated with this virus and possible ways of excluding it from potential donor animals is still unidentified.

Finally, in relation to *agricultural applications*, a number of studies examining the biological and biochemical properties of products from cloned animals in relation to risks to human health have already been published. The differences in meat samples taken from embryonic cloned, somatic cloned and non-cloned cattle have been examined with no significant biological differences. Examinations of the nutritional value of milk and meat products derived from cloned cattle were reviewed with no significant differences in products from cloned and non-cloned animals. Although the amount of research in this field is still limited it seems that products from cloned animals do not pose any risks to human health, although both the limited amount of research and the methodological limitations in the research should be taken into account.[9]

[8] Opinion of the group of advisers on the ethical implications of biotechnology to the European Commission. *Ethical aspects of genetic modification of animals*, 29 September 1992, Section 2.1.

[9] See actual references and more elaborate discussion of the state of knowledge regarding risks in the report: *The science and technology of farm animal cloning. A review of the state of the art of the science, the technology, the problems and the possibilities*

Risks related to farm animal cloning

Risk assessment and ethical values
The risks related to farm animal cloning can be divided into three categories. Risks to human health, risks to the environment and risks to animal welfare. These can again be divided into many subcategories. It should be noted from the outset that the concept of risk is not an unambiguous concept. Thus the factors that one choose to take into account, the methodologies chosen to assess their relevance and likelihood and the overall evaluation of what is acceptable and unacceptable risks are based on underlying value judgments that reflects the ethical perspective of the risk evaluator. Prior to any risk evaluation lies thus a series of decisions based on ethical values understood in broad sense as the kind of values that influence human choices.

Within all three main categories of risks, it can be debated what kind of entities should be included as relevant possible bearers of risks and what aspects of their existence it is relevant to consider. Thus it can be argued that within the category of human health one should only look for negative physical consequences of consuming products form cloned animals or their off-spring or it can be argued that also the social and economical importance of farm animal cloning should be assessed, since changes caused in the social and economical sphere also will affect people´s lives and thereby have an effect on their over-all well-being. Crucial here is the definition of human health that is chosen at the outset. It could also be discussed whether the changes in human attitudes towards nature that farm animal cloning may cause or support should also be assessed within this category. Finally it is of course of the outmost importance what time-frame is chosen. Is it only short term consequences of introducing the technology that is to be considered or should more long-term consequences also be considered?

In the case of the environment one of the really difficult questions to answer is, whether changes in the environment caused by farm animal cloning should only be assessed on the basis of the possible detrimental effects on humans or also on the basis of detrimental effects on the environment even if these effects are inconsequential or even positive to humans. Another question is the question about the period of time that should be assessed, just as it is important to decide to what extent changes in the environment might be detrimental to humans and/or the environment itself. Finally it is of the outmost importance to decide what is actually understood by the term environment. Is it wild living relatives of the cloned animals – and if so are only the risks to the individual animals to be assessed or should the risk to the species as such be included in the assessment? Or should perhaps also other species and kinds of lives as for example plants and plant species be included? And should the effects on local ecosystems and the biosphere as such also be assessed. Some of these questions will answer themselves in the concrete cases, but still it should be clear that a series of choices that will be based on ethical values must be taken prior to any kin of risk assessment.

The same truth holds when we turn to animal welfare. Again we find different attitudes about what constitutes animal welfare. Should only risks that animals might experience physical pain be assessed or should concepts like naturalness and welfare be included in the assessment. The questions about different attitudes towards what time horizon one should work within and different perceptions of whether only effects on animal welfare that have a detrimental effect on humans should be taken into account or whether such effects have importance in themselves, will also have to be answered.

Existing work
So far only few studies related to the risks of farm animal cloning has been published. These studies mainly focus on the composition of products (milk and meat) form cloned animals or their off-spring and on the physical effects that the cloning technology (SCNT) has on the physical welfare of the animals. In this latter category the focus is usually to identify reasons for the low efficiency of the technology both prior to implantation of embryos in surrogate mothers and after birth.

Studies into the composition of meat and milk have revealed none or only small differences between products from non-cloned animal and animals that have been cloned or their off-spring. Whether the changes that have been found constitute any risk to the physical health of humans is still unclear, but in the literature the risks of this are usually evaluated to be very low. As stated above only few studies have been conducted so far, but it is worth noticing that they all, so far, point in a direction where the risks to human health from consuming products form cloned animals or their off-spring are seen as virtually non-existing. The studies into the effects of cloning on the animals ranging from the embryos in vitro to the developing animal in the uterus of the surrogate mother and to the born animals show that the technology has a substantial impact. The success rates of cloning, measured as the amount of healthy animals born are still somewhere around 5% depending on the species. Only few of the cloned embryos develop into viable embryos that can be transferred to an uterus and of these only few are born and of these many experience welfare problems. The welfare problems for the animals in vivo is usually collected under the heading of Large Offspring Syndrome that among other things encompass an unacceptably high level of losses during early and late pregnancy, stillbirths, early postnatal deaths, short lifespan, obesity and malformations. The reasons for these problems are still poorly understood and much research effort goes into understanding the reasons behind the low efficiency of the technology to make it a viable economical alternative to other kinds of animal reproduction. *More information*[10]

[10] The connection between values and assessment of risks regarding farm animal cloning: see the report: *Farm Animal Cloning and Ethics. Identifying the Scope of the Discussion - A Literature Review* from the project CLONING IN PUBLIC.

The European Commission has funded two projects under the Fifth Framework Programme examining the issues surrounding animal cloning.[11] The first concluded that there was a need for the technology to be refined, the risks to be limited and public acceptability gained before animal cloning could be commercially deployed. It also called for a permissive regulatory environment. The second identified a lack of consensus in the area. Research on animal cloning continues within the EU at a number of centres, subject to existing legislation on the use of animals in research, in particular Directive 86/609/EEC of 24 Nov. 1986 on the protection of animals used for experimental and other scientific purpose. In Europe, animal cloning remains, for the moment, very much a research activity. However, elsewhere in the world agricultural applications are further advanced.

EU regulation and measures of harmonisation
This section also includes relevant conventions of the Council of Europe, since they apply both to EU Member States and to European states outside the EU. There is no direct EU legislation on cloned animals. The following list includes main regulatory mechanisms which may indirectly apply to activities related to animal cloning and regulations relating to genetically modified organisms, since animals used as bioreactors or models of human disease may be both genetically modified and cloned.

Council of Europe Conventions

- European Convention on the Protection of Animals kept for Farming Purposes, 1976 (ETS 087)
- European Convention for the Protection of Vertebrate Animals used for Experimental and Other Purposes, 1986 (ETS 123)
- Protocol of Amendment to the Convention ETS 123, 1998 (ETS 170)

EU legislation and regulations relating to animal welfare

- Directive 86/609/EEC of 24 Nov. 1986 on the protection of animals used for experimental and other scientific purposes
- Protocol on the protection and welfare of animals to the Treaty of Amsterdam amending the Treaty on European Union, the Treaties establishing the European Communities and certain related acts, signed on 2 October 1997
- Directive 98/58/EC concerning the protection of animals kept for farming purposes
- Decision 2003/584/EC concerning the conclusion of the Protocol of Amendment to the European Convention for the protection of vertebrate animals used for experimental and other scientific purposes

EU legislation and regulations relating to genetic resources and genetic modification

- Regulation (EC) No 870/2004 of 24 April 2004 establishing a Community programme on the conservation, characterisation, collection and utilisation of genetic resources in agriculture and repealing Regulation (EC) No 1467/94
- Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EC

[11] Claxton, J., Sachez, E. and Matthiessen-Guyader, L, 2004. Ethical, legal and social aspects of farm animal cloning in the 6th framework programme for research. *Cloning and Stem Cells* 6: 178-181.

- Regulation (EC) No 1830/2003 concerning the traceability and labelling of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC
- Regulation (EC) No 1829/2003 on genetically modified food and feed
- Regulation (EC) No 65/2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms
- Regulation (EC) No 641/2004 on detailed rules for the implementation of Regulation (EC) 1829/2003
- Recommendation 2004/787/EC on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) 1830/2003

EU food regulations

- Regulation 258/97/EC concerning novel foods and novel food ingredients
- Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs
- Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[12]

EU intellectual property legislation

- Directive 98/44/EC on the legal protection of biotechnological inventions
- European Patent Convention 1973 (EPC) – this enables patents to be obtained in European states that are members of the European Patent Organisation (not all of which are currently in the EU) based on a single application

Other EU Rules

In supporting scientific research through its Framework Programmes the European Commission has established and ethical and legal framework which grant applicants have to follow.[13,14] For proposals which include the use of animalsand, particularly the use of transgenic animals or the cloning of animals, the scientific evaluation is followed byan ethical review, carried out by a multidisciplinary panel of independent experts.[15] The ethical review panels aim to ensure that researchers adhere to the ethical rules set out by the Commission.[16] Principally these ensure that scientists are aware of the relevant EU, national legislation and codes and that the proposed research does not conflict with this. Ethical review panels will also comment on and make recommendations about other ethical aspects of research projects. Under the 6th Framework Programme Integrated Projects and Networks of Excellence funded within the thematic areas of research are encouraged to take on board specific research and stakeholder groups to study the ethical impact of the research undertaken, as part of an integrated approach in dealing with of ethical, legal and social aspects of research.

[12] In addition, other food related directives/regulations apply (food control, food hygiene, food contaminants, specific foodstuffs regulations etc.).
[13] http://europa.eu.int/comm/research/science-society/ethics/ethics_en.html
[14] Ibid.
[15] Ibid.
[16] http://europa.eu.int/comm/research/science-society/ethics/research-fp6_en.html

3.2 Other international regulation

More and more animal cloning activities are reported to be taking place outside the EU. In particular, the US, Australia, New Zealand and several Asian countries, including Japan, South Korea and China, are making advances in farm animal species cloning.[17] In some of these countries it seems likely that cloning and sales of cloned-derived products in home markets will be allowed. This will present a WTO challenge.

Efforts by EU countries to prevent these products entering European markets with the stated aim of protecting consumer interests will probably depend on the WTO interpretation of the precautionary principle, and on what is seen by the WTO as a legitimate concern. Normally, health risks and risks to the environment are viewed as legitimate interests. Hence these risks can be invoked to prevent or regulate, for example, the movement of living animals and animal products across national borders. The WTO has not recognised animal welfare in its negotiations. However, the Organisation International des Epizooties (OIE, the animal world health organisation) has adopted a resolution on welfare and is in the process of developing policies to make recommendations of international legitimacy.[18] In paragraph 8 of the resolution it is stated that the OIE also considers the animal welfare aspects as issues that "… arise in the areas of genetic modification and cloning, genetic selection for production and fashion, and veterinary practices.". The EU supports the inclusion of animal welfare in trade issues.[19]

For a more detailed description of the international regulation, including the legislative status in countries outside the EU, please refer to Section 4.2 in this report and see chapter 5 for issues of intellectual property protection, i.e. the patenting of biotechnology. In this report, please refer also to Section 2.1 on international regulatory mechanisms as well as Section 6.1 on the free movement of goods and international trade

[17] It is, however, difficult to obtain validated information on the type and extent of regulatory framework in these countries.

[18] OIE resolution No. XIV, Animal Welfare Mandate of the OIE. Adopted by the International Committee of the OIE on 29 May 2002. Resolution No. XXVI of 25 May 2004 recognised that work on developing guidelines for animal welfare priority topics was already underway.

[19] Claxton, J., Sachez, E. and Matthiessen-Guyader, L, 2004. Ethical, legal and social aspects of farm animal cloning in the 6th framework programme for research. *Cloning and Stem Cells* 6: 178-181.

4. National legislation, other legal frameworks and actual regulatory practice

Most countries in the world have no specific legislation on the cloning of farm animals. In some cases, however, legislation covers cloned as well as genetically modified animals. In several countries, at present, legal frameworks from other areas are taken to regulate farm animal cloning. Only in Norway (2004) and Denmark (2005), has specific legislation on animal cloning recently been passed.

4.1 European countries

Farm animal cloning research is proceeding in several European countries. However, most European countries have no specific legislation prohibiting the cloning of animals, including farm animals. Instead, cloning is most often regulated, where it is, through other regulatory frameworks – through regulatory mechanisms covering, for example, the protection of animals and animal research. In many European countries experiments with animal cloning have to be approved by the authorities. The first European country to issue legislation on animal cloning was Norway; Denmark was the first EU member state to do so.

Table 1 shows the status of current national legislation and actual practice in a number of European countries. Please note that the list is not exhaustive. The questions asked, in connection with individual countries, were:

- Does your country have laws regulating animal cloning (including embryo splitting and cloning by nuclear transfer)?
- If yes – what do these laws say?
- If no – are there plans for regulating animal cloning in the near future?
- Irrespective of your answer to the first question above, are animals being cloned for research purposes (either by embryo splitting or by nuclear transfer)?
- If yes – what kinds of animal, and how many?
- What is the procedure for obtaining permission to perform scientific experiments involving animal cloning?

Table 1. Status of farm animal cloning regulation in *selected* countries within Europe (additional information is given on countries marked *)

Country	Specific animal cloning legislation?	Other legislation regulating animal cloning	Plans for regulating animal cloning?	Procedure for obtaining permission for scientific experiments
Czech Republic	No	No	Currently discussions in Parliament	Approval required from the Central Commission for Animal Protection
Denmark*	Yes, covering all kinds of cloning process	Indirectly through animal welfare and animal experiment legislation	No, a bill on cloning and genetic modification of animals has been issued in June 2005, to be enacted October 2005	License from the Animal Experiments Inspectorate is required
Estonia	No	N/A	N/A	N/A
Finland	No	Indirectly through animal protection and welfare legislation	No	Approval from either ethical committee or state agency
France	No	N/A	N/A	Evaluation by INRA ethical committee
Germany*	No	Indirectly through animal protection and welfare legislation	N/A	Permission according to animal protection law; administrated by local animal welfare committees
Greece	No	N/A	No	There are committees in each university that oversee research on animals and humans (but at present there is no cloning of animal for research purposes)
Hungary	No	N/A	N/A	N/A
Italy	No	Indirectly through Italian legislation on animal protection	No	Has to meet the Italian requirements for animal experimentation
Norway*	Yes. Cloning of vertebrates and crustaceans is prohibited, and cloning of primates is prohibited without exemptions	No	No, in 2004 the existing act on gene technology was amended with a number of provisions regarding animal cloning	Dispensation for basic biological and medical research is possible
Portugal	No	N/A	N/A	N/A
Spain	No	Indirectly through the law on animal experimentation and law about transgenic animals	Under consideration	Permission needed from institutional ethical committee
Sweden	No	Indirectly through animal protection/welfare legislation	No, animal cloning of farm animal species is not pursued in Sweden	Approval from Ethical committee, surveillance by Swedish Animal Welfare Agency
The Netherlands*	No	Indirectly through the Animal Health and Welfare Act	N/A	Permission by Ministry of Agriculture
United Kingdom*	No	Indirectly through animal protection law	No	Approval by the Home Office

N/A – Information not available.

Denmark

In June 2005 Denmark was the first EU member state to issue legislation specifically regulating all varieties of animal cloning - including SCNT, embryonic cell cloning and embryo splitting.[20] The legislation allows for the cloning of animals for specifically mentioned purposes. Until 2005 in Denmark, as in most other countries, animal cloning had not been specifically addressed in law. It was covered by general animal welfare legislation (The Animal Welfare Act and the Animal Testing Act) and, where it involved genetic modification, the Gene Technology Act. However, political concerns about animal cloning were expressed in a parliamentary motion in May 1997, and the parliament encouraged the Government to issue rules and regulations on animal cloning.[21] As part of this motion the parliament expressed its aspiration to restrict animal cloning to a research setting. The parliament also stated that research in cloning should not result in a fully developed animal. Although there has been some debate as to whether this statement is legally binding, it has been respected in practice.[22] Consequently, research on animal cloning has been performed, but until now no cloned offspring has been born; the pregnancies have been terminated before delivery.

Following parliamentary debate in November 2002 the Parliament encouraged the Government to set up a preparatory committee to follow up on the motion of May 1997. In October 2003 this committee issued a report with recommendations on future regulation of animal cloning and accompanying technologies.[23] In the committee's opinion any use of biotechnology on animals, including cloning and genetic modification, should respect the principle of proportionality. This means that the negative consequences of the technology, in reduced animal welfare and increased risk of damage to the environment, should be balanced against its advantages, such as, for example, new treatments of diseases in humans and animals. Making this assessment, the committee could support the application of cloning and genetic modification techniques to animals in connection with research that may lead to important knowledge of diseases in humans and animals. But the committee did not believe it to be it justifiable to use these techniques on production of animals for production of food and other agricultural products. Against this background the committee recommended that the existing legislation be supplemented by specific rules on the cloning and genetic modification of animals (including import and breeding) which restrict use of these techniques to situations where it serves an essential purpose such as basic research and applied research aimed at improving health and environment.[24]

In response to the recommendations, the Government issued a bill on cloning and genetic modification on animals in February 2005. [25] This was passed in June 2005.[26] According to

[20] Lov om kloning og genmodificering af dyr m.v. af 14. Juni 2005 [Animal cloning and genetic modification Act of 14 June 2005].
[21] Motion of 23th May 1997.
[22] A parliamentary motion is normally considered to be binding for the government until the next general election, whereas it is disputed whether it is binding after a general election.
[23] Ministeriet for Videnskab, Teknologi og Udvikling, "Genmodificerede og klonede dyr", 2003. There is an English summary in the report.
[24] The committee did not have a unanimous position on how to define an "essential purpose". One member had a more restrictive position that the other committee members
[25] Justitsministeriets lovforslag L 8 om kloning og genmodificering af dyr m.v.
[26] Act no 550 of 24 June 2005

section 1 of the Act cloning and the genetic modification of animals must only take place if they are considered to be of substantial benefit, and only with one of the following purposes:

- performing basic research
- performing applied research aiming to improve health and the environment
- creating and breeding animals producing substances essentially benefiting health and the environment
- teaching at institutions of higher education, and the training of persons who are to carry out these techniques

Furthermore, a license from the Animal Experiments Inspectorate is required in each case, irrespective of whether the activity can be categorised as "animal testing" under the Animal Testing Act. These requirements also apply to the breeding of cloned or genetically modified test animals and where a previously cloned or genetically modified animal is used for research purposes. On the other hand, the import and breeding of cloned or genetically modified animals for purposes other than animal experiments (e.g. food production etc.) is not covered by the Act. This delimitation is required by the EU directive on deliberate release, according to which national restrictions on the import, deliberate release and marketing of genetically modified organisms (including animals) are not permitted.[27] The directive does not cover cloned animals that are not genetically modified, but to ensure that there is harmonious legislation the same regulation apply to cloned animals. However, during the legislative process it was discussed how to regulate the import of non-genetically modified cloned animals and it was promised that the Ministry of Family and Consumer Policy would issue administrative regulations requiring the authorisation from the Animal Experiments Inspectorate in cases of import of cloned animals. This authorisation will only be given if the animal is imported for research purposes and only in cases where the research project fulfils the "substantial benefit" requirement.

Germany
There is no specific legislation on cloning of animals in Germany. The two statutes on the protection of animals (the Animal Breeding Statute and the Animal Protection Statute) do not mention cloning, and animal cloning research is not covered. However, the current regulatory status is that a prohibition of animal cloning research is considered a restriction of the liberty of science and therefore a violation of the German constitution.

Norway
In May 2004 Norway became the first European country to issue legislation on animal cloning. The Norwegian Parliament amended the existing act on gene technology with a number of provisions on animal cloning.[28] Section 11a of the Act, the main provision, prohibits the cloning of vertebrates and crustaceans, but it is possible to have a dispensation for basic biological and medical research and other medical activities if the purpose is to obtain new knowledge of medical treatment or prophylactics for humans and animals. On the other hand, the cloning of primates is prohibited without exemption. The restrictions on

[27] Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council directive 90/220/EEC
[28] Act No 22 of May 7 2004 amending Act No 38 of April 2 1993

animal cloning do not cover cloning processes which could take place in nature (embryo splitting).

Before a dispensation is issued, the possible benefits should be balanced against the burdens placed on the animals with regard to integrity, instincts, welfare etc. Thus Norwegian law, like Danish law, emphasises respect for animal integrity as an independent value that goes beyond welfare. Furthermore, the *travaux préparatoire* emphasises that a major purpose of the act is to prevent the cloning of human beings. This explains the severe restrictions on the cloning of primates.

The Norwegian legislation only covers the production of cloned animals. Imports of cloned animals are not covered.

The Netherlands
No specific legislation exists. Cloning of animals is regulated via what can be deduced from the Animal Health and Welfare Act of 1992. All biotechnological animal experiments, including cloning by nuclear transfer, have to be approved by the Ministry of Agriculture, Nature Protection and Fisheries. The ministry counsels the Committee for Biotechnology on Animals. Experiments are not required to be for scientific research purposes, but they must have substantial societal relevance. Moreover, there should be no alternatives to reach the goal of the research or application, and the importance of the research or application must outweigh the possible damage to the health, welfare and integrity of the animals. Since 1997, only one cloning permission has been granted (for research on the production of human collagen type II in milk from genetically modified cows).

United Kingdom
There is no specific legislation in the UK addressing animal cloning. The Animals (Scientific Procedures) Act 1986 (ASPA) controls the use of animals for scientific procedures including the breeding and supply of supply of animals for such use. The Act also covers the breeding of animals with harmful genetic defects and the creation and breeding of genetically modified animals. A procedure is also regulated if it is part of a set of otherwise unregulated procedures which, in combination, may compromise the health or welfare of a protected animal. As the cloning of farm animals is still considered experimental in the UK, this procedure would fall under the Act. The ASPA is administered by the Animal Procedures Section of the Home Office, which is responsible for policy on the use of living animals in scientific procedures. The Animals (Scientific Procedures) Inspectorate is responsible, under the terms of the Act, for assessing licence applications, applying special terms where necessary, and monitoring and reviewing them, and for visiting establishments where scheduled animals are kept or bred. Independent advice on ASPA is provided to the Home Secretary by the Animal Procedures Committee, a statutory advisory non-departmental body which is required, in its advice, to balance the needs of science and industry against the welfare of the animals used.

The UK has no national ethics committee but the Nuffield Council on Bioethics has recently published a report, *The Ethics of Research Involving Animals*,[29] which, although it does not

[29] http://www.nuffieldbioethics.org/fileLibrary/pdf/RIA_Report_FINAL-opt.pdf

address animal cloning directly, addresses activities that might involve cloned animals, such as the use of animal models for human disease and genetic modification of animals.

The welfare of farmed animals is covered by Welfare of Farmed Animals (England) Regulations 2000 (S.I. 2000 No. 1870), which came into force on 14 August 2000. These regulations replaced the Welfare of Livestock Regulations 1994 and the Welfare of Livestock (Amendment) Regulations 1998. They implement EU Council Directive 98/58/EC, the so-called 'general directive', in English law. Separate but similar legislation applies in Scotland, Wales and Northern Ireland. These regulations cover all farmed animals. Schedule 1 (which does not apply to fish, reptiles or amphibians) contains specific requirements pertaining to inspections, record-keeping, freedom of movement, buildings and equipment and the feeding and watering of animals.

To summarise, in most countries there is no legislation directly prohibiting the cloning of animals, and hence farm animals. Instead – where it is regulated at all – cloning is indirectly regulated through laws on the protection of animals and animal research legislation. As with other types of animal experimentation, experiments connected with the cloning of animals have to be approved by the relevant authorities.

To date, Denmark and Norway are the two only European countries to have taken legislative initiatives on animal cloning and to have passed cloning legislation.

4.2 Countries outside Europe

Like their European counterparts, the major, research-heavy countries (the US, Canada, Australia, China and Japan) have no specific legislation on animal cloning. Japan has significant farm animal cloning activities; likewise South Korea and China.

Table 2 presents an overview of the status of the regulatory approach in *selected* major countries outside Europe involved in animal cloning.

Table 2. Status of farm animal cloning regulation in *selected* countries outside Europe (additional information is given on countries marked *)

Country	Specific animal cloning legislation?	Other legislation regulating animal cloning	Plans for regulating animal cloning?	Scientific experiment permission practice
Australia*	No	No national regulation concerning the use of animals for scientific purposes, including cloned animals	Yes, different initiatives exist at state level and through a new animal welfare law	Animal Ethics Committees (AEC) at the state level must approve scientific procedures
Canada*	No	Regulation based on end products. Indirectly regulated through the Canadian Environmental Protection Act	Yes, possible regulation by law of cloned animals	All animal experimentation, including cloning research, has to be approved by animal experimentation committees
China	N/A	N/A	N/A	N/A
Japan*	No	N/A	N/A	N/A
New Zealand*	No	To some extent regulated through animal welfare legislation	Yes, possible amendment of legislation following the UK model	Approval needed from a local Animal Ethics Committee (AEC).
South Korea*	No	No	Yes, a unified bill on bioethics issues	N/A
United States of America*	No	Regulation is based on legislation covering end products	Not for the cloning process, but for a regulatory and assessment framework for end products	US Food and Drug Administration (FDA).

N/A – Information not available.

Australia

There is no direct regulation of farm animal cloning. Australia has two main instruments with which to control animal biotechnology. First, gene technology is regulated by the National Office of Gene Technology Regulator (OGTR) in accordance with the Gene Technology Act 2000 (with amendments). Second, the use of animals in science and in commercial applications is regulated by each state/territory government in line with Commonwealth legislation. In some states, such as Victoria, a more complex system of committees is used to control biotechnology.[30] However, the Gene Technology Act does not cover projects involving animal cloning (without genetic modification), and cloned animal use and its impact is not recorded by the National Office of Gene Technology Regulator. Thus, cloned animals which have not been genetically modified are covered neither by the provisions of the Australia New Zealand Food Standards Code nor by State and Territory Food or Health Acts.[31]

The Gene Technology Act contains almost no regulation of animal welfare. It merely states that the membership of the national Gene Technology Ethics Committee must include someone with experience in animal health and welfare. At the state level – for example, in Victoria – legislative control of the welfare of cloned animals used in scientific procedures is

[30] Blaszak, K. 2004?. The governance of welfare of animals involved in biotechnology in Victoria – current regulatory framework, relevant committees and emerging issues. Bureau of Animal Welfare, Department Primary Industries.

[31] The Code is adopted as the required standards for food produced in New Zealand and the states, territories and Commonwealth of Australia in relation to food sold and/or imported into both countries.

part of the Prevention of Cruelty to Animals Act from 1986. Regulation of animals in science is state-based. There is currently no national regulation of the use of animals for scientific purposes, including cloned animals. The Animal Ethics Committee (AEC) approves scientific procedures at state level. The AEC must comply with The Australian Code of Practice for the Care and Use of Animals for Scientific Purpose, prepared in 1986. In cloning projects, the AEC must get documentation from investigators on the actual cloning of the animals in order to establish humane end points and analyse actual 'costs' to the animals as any adverse effects are realised.

As applications become more realistic, and cloned animals are no longer only used for scientific experiments, but are released into the environment to become part of agriculture or other industries (cf. New Zealand), the question is whether the legislation in place is sufficient to adequately protect or regulate the welfare of cloned animals for commercial production purposes. A prospective new animal welfare law makes explicit reference to animal cloning. At the state level – for example, in Victoria – welfare would be regulated through the Prevention of Cruelty to Animals Act; but here amendments may be needed.[32] The Australian government has initiated a policy process to develop a government position on the sale of non-GM cloned animals (including their offspring) as food.

Canada

There is no direct regulation of farm animal cloning. A form of regulatory monitoring of animal biotechnology exists, but there is no established policy or specific regulatory approach to animals and the products derived from these. Under the 1999 Canadian Environmental Protection Act, SCNT-cloned individuals (i.e. individuals cloned by single cell nuclear transfer) and offspring produced from originally cloned animals may be considered "new". This may imply that such animals require notification In line with the New Substances Notifications Regulations under the Canadian Environmental Protection Act. Health Canada's Bureau of Food Policy Integration has considered a request for the marketing of meat from cloned animals and their offspring. Its interim policy is to treat food produced from SCNT-cloned animals as novel foods. However, developers who wish to use SCNT to produce livestock for food should withhold novel food notifications until safety assessment guidance is available.[33] All animal experimentation, including cloning research, has to be approved by animal experimentation committees. A ministerial working group is preparing a report on animal cloning as the basis for a decision on possible regulation by law of cloned animals. No decision has yet been made.

[32] Blaszak, K. 2004. The governance of welfare of animals involved in biotechnology in Victoria – current regulatory framework, relevant committees and emerging issues. Bureau of Animal Welfare, Department Primary Industries.

[33] Bourbonnière, L. 2004. SCNT cloning: What are the SCNT cloning: What are the issues? Canadian Food Inspection Agency, Animal Health and Production Division.

Japan
Currently, no legislation or governmental guidelines on animal cloning operate.[34] In 2000 the Science Academy of Japan set up a committee to assess cloning applications and issued a report on the guidance of research on animal cloning with an commercial perspective . However, commercial application in breeding and the food industry is yet to come.[35] In 1997, the government's Council for Science and Technology Policy published a report entitled "The Basic Plan on Life science Research and Development". This stated that the cloning of farm animals should be promoted because it would not affect issues of human ethics directly. Japan currently has the largest number of cloned cows in the world. Since 1990, more than 1000 animals have been cloned using somatic cell cloning and egg cloning in cows, pigs and goats. Recently, the Japanese the Ministry of Agriculture, Forestry and Fisheries announced that beef and milk from cows cloned from the cells of adult animals are safe. The US. government is preparing to lift a ban on the use of cloning technology to develop high quality cloned cows. However, the US is asked to take measures to prevent beef from cloned cattle from being mixed in meat shipped to Japan,[36]

New Zealand
There is no direct regulation of farm animal cloning. Two pieces of legislation in New Zealand have an important regulatory impact on biotechnology: the Hazardous Substances and New Organisms Act 1996 and the Animal Welfare Act 1999. Moreover, two ministerial advisory committees, the National Animal Ethics Advisory Committee (NAEAC) and the National Animal Welfare Advisory Committee (NAWAC) provide independent advice on animal welfare and ethical issues arising from research on, and uses of, biotechnology.[37] The Hazardous Substances and New Organisms Act 1996 covers neither cloning nor products derived from clones. According to the Animal Welfare Act 1999, animals used for the purpose of research or for the production of biological products should be treated in accordance with an approved Code of Ethical Conduct and only after approval has been given by a local Animal Ethics Committee (AEC). The existing New Zealand regulatory systems have been characterised as a relatively "low bureaucracy" framework.[38]

In 2002 the NAEAC gave the Government's biggest science company and their partner Australian company a license to clone livestock commercially in New Zealand.[39] The NAEAC is currently considering recommending modifications to existing legislation in keeping with the model of UK legislation.

South Korea (officially the Republic of Korea)
There is no legislation prohibiting animal cloning in South Korea. South Korea was the fifth country in the world to clone animals. In South Korea, bills are of two types: Government bills and the National Assembly bills. Twelve attempts were made to legislate on bioethics

[34] Kimora, N. 2005. Embassy of Japan, United Kingdom, personal communication, May 2005.
[35] Mouquet, P. 2004. Le clonage animal au Japon. Ambassade de France au Japon, 2 pp. Available online at http://www.bulletins-electroniques.com/japon/rapports/SMM04_061/maincell.htm.
[36] *Tokyo Shimbun*, July 5, 2005.
[37] Bayvel, A.C.D. 2004. Animal use in biotechnology: Issues and options – a New Zealand perspective. *ATLA* 32, Supplement 1: 377-381.
[38] Bayvel, A.C.D. 2004. Animal use in biotechnology: Issues and options – a New Zealand perspective. *ATLA* 32, Supplement 1: 377-381.
[39] Seamark, R.F. 2003. Review of the current status of the extent and use of cloning in animal production in Australia and New Zealand. SA Consulting.

issues between 1997 and March 2003. However, all failed.[40] The first National Assembly bill on bioethics issues in South Korea was proposed in 1997. It was one of the revised bills on the Genetic Engineering Promotion Law. The bill disallowed any financial support of human cloning. The South Korean government has recently submitted a unified bill on bioethics issues to the National Assembly.

United States of America

There is no legislation directly controlling animal cloning. In general, the American authorities directly regulate *products* rather than processes, so cloning is indirectly regulated in the US on the basis of the intended use of the cloned animal.[41] This is comparable with the EU situation on food area where the Novel Food Regulation (EC) No 258/97 regulates food via the effects of the process (here: cloning) on food. The food (and not the process) needs to meet standards. In the US, laws applying to a particular species would also apply to its clones, and laws that apply to laboratory animals would apply to lab animal clones.[42] Moreover, if an animal was to be cloned for food-use, the cloned product would have to meet food safety standards; if it was cloned to produce pharmaceuticals, the finished drug products would have to meet drug standards; and if the cloned animal had a xenotransplantation purpose, the body part in question would need to meet biologics regulation.[43] Please note, that the listed purposes do not imply imminent commercial application within these fields.

Regulation is principally is through the US Food and Drug Administration (FDA). The FDA is studying the risks, to determine how to manage them, in two strands of risk assessment. One describes the potential risks, if any, of consuming food products from animal clones and their offspring. The other characterises health risks to animal clones and their offspring. On the basis of this approach, science-based regulation, in the form of policy or industry guidance, is being elaborated.[44] The risk assessors are expected to report in 2005.

[40] Sung-Goo, H., Young, J.Y. and Wha-Joon, R. 2003. New Cloning Technologies and Bioethics Issues: The Legislative Process in Korea. *Eubios Journal of Asian and International Bioethics* 13: 216-219.

[41] Marden, E. 2005. Sidley, Austin, Brown and Wood LLP. Personal communication, March 2005.

[42] Rudenko, L. 2005. The Center for Veterinary Medicine (CVM), US Food and Drug Administration (FDA), personal communication, May 2005.

[43] Biologics are medical products derived from living sources. They include vaccines, blood and blood derivatives, allergenic patch tests and extracts, tests to detect HIV and hepatitis, gene therapy products, cells and tissues for transplantation, and new treatments for cancers, arthritis, and other serious diseases.

[44] Bren, L. 2003. Cloning: Revolution or evolution in animal production? *FDA Consumer* May/June.

5. Intellectual property protection: patenting biotechnology

Although patent law is considered to be one of the most internationally harmonised legal areas, there are some uncertainties regarding the intellectual property protection of genetic and biological material. These uncertainties exist at both the international and EU level. They concern the ownership and patentability of the basic process of producing cloned animals through nuclear transfer, the patentability of animals created thereby, and the patentability of derived products.

Patents are a division of intellectual property law. Patents recognise that some types of intellectual property should be granted legal protection. The patent itself is a form of contract between the inventor and the government. The contract grants the inventor the right to prevent others from exploiting the invention for a limited period of time (normally 20 years). In return, the inventor makes full public disclosure of the invention. In relation to modern biotechnology, some of the key intellectual property protection questions are:

- How can traditional principles of patentability be applied to new forms of technology?
- Can property rights be granted over genes? Are the products of modern biotechnology inventions or mere discoveries (and thus not patentable)? European courts seem to have questioned the suitability of patenting modern biotechnology products.[45]
- Which international conventions and treaties address biotechnology, and in particular animal cloning?
- Is there a European directive in place?
- Does patent law cover the subject of animal biotechnology and animal cloning?
- What steps have been taken to harmonise patent law when it comes to animal biotechnology?

5.1 International patent law

The basic international patent law agreement is the Paris Convention for the Protection of Industrial Property (1883), a Convention which has been ratified by over 100 countries and led to the development of the World Intellectual Property Organization (WIPO).[46] The Budapest Treaty 1977, ratified by some 30 countries, was for nearly 25 years the only treaty to deal exclusively with patents on living matter (albeit only with the patent filing procedure).[47] Under the auspices of WIPO, and a Patent Law Treaty from 2000, work has

[45] Zekos, G.I. 2004. Patenting biotechnology. *Journal of Information, Law and Technology (JILT)*. 2004(1), 29 pp.

[46] The EC as such is not a member of WIPO but all member states are parties to the organisation.

[47] Opinion on ethical questions arising from the Commission proposal for a Council directive on legal protection for biotechnological inventions. Opinion of the group of advisers on the ethical implications of biotechnology to the European Commission. 30.09.1993.

started on the Substantive Patent Law Treaty (SPLT) which is designed to harmonise patent law and in particular inventions in the field of biotechnology.[48]

Several bodies at the international level (beyond the EU) are currently looking into the question of protection of biotechnological inventions. These bodies include the Council of Agreement on Trade-Related Aspects of Intellectual Property Rights (WTO TRIPS, from 1994) and the Food and Agriculture Organisation's (FAO's) Committee on Agriculture (COAG).

There are tensions between the granting of intellectual property rights under TRIPS and the objectives of the Convention on Biological Diversity, signed in Rio de Janeiro in 1992, esp. Article 16(4) and 16(5).[49] The Substantive Patent Law Treaty aims to fit in with the TRIPS agreement, the Patent Law Treaty and the Patent Cooperation Treaty (PCT). A major criticism of the existing TRIPS agreement is that it forces all countries to accept an array of biotechnological patents covering genes, cell lines, organisms and living processes. Some observers wish to see a ban on patents on nuclear transplant cloning and other reproductive technologies, and on the cloned animals and lines produced.[50]

In general, patents apply in the country in which they were granted. The main Convention at the European level is the European Patent Convention (EPC), which came into force in 1978. This now has 26 signatory states. With this Convention it became possible to obtain patents in all European states that are member of the European Patent Organisation (most of which are currently in the EU) using a single application. Disputes and challenges to patents take place in national courts.[51]

As a result of multiple international harmonisation measures, patent law is very uniform around the world. Thus statements about the criteria of patentability represent the legal position in most states.[52] However, there is significant difference between Europe and the US: in Europe patentable products require an 'inventive' step; in the US the focus is on 'non-obviousness' (which means that so long as the particularities of the result are not obvious to an expert, the criterion is satisfied). The latter represents a lower threshold for patentability.[53]

5.2 European level

In the EU, the main legal text is the directive 98/44/EC on the legal protection of biotechnological inventions (hereafter: the Biotechnology directive).[54] This was adopted after

[48] As noted in the Report on the Development and Implications of patent law in the field of biotechnology and genetic engineering from 2002 of EC, a similar excercise has been embarked upon in 1980s and had ended in failure in 1991.

[49] Some of the unresolved issues include conflict of rationale, origins and overall framework, the issue of patents on life, national sovereignty vs. rights of IPR holders, and prior informed consent of states and communities vs. unilateral patents.

[50] Cf. e.g. http://www.i-sis.org.uk/index.php.

[51] Laurie, G. 2003. Intellectual property protection of biotechnological inventions and related materials. Innogen working paper 4.

[52] Laurie, G. 2003. Intellectual property protection of biotechnological inventions and related materials. Innogen working paper 4.

[53] See also Suk, J. 2004. FDA regulation of biotech/genomics drugs: A scoping report for Innogen. Innogen working paper 13.

[54] Directive 98/44/EC on the legal protection of biotechnological inventions of the European Parliament and of the Council of 6 July 1998, OJL 213, pp. 13-21, July 30, 1998.

more than 10 years of debate.[55] At the heart of the discussions was the need to balance the establishment of a legal framework allowing European businesses to develop in a rapidly developing sector and the prevention of "malfunctions".[56] The stated aim of this directive on biotechnology patenting, implemented in large part (Articles 1 to 11) by the Patents Regulation 2000, is to harmonise existing international conventions and the requirements for patentability of biotechnological inventions between Member States. The Member States were required to incorporate the directive into national law before July 2000.[57]

The Biotechnology directive appears to be the first international text to deal specifically with biotechnological inventions. One of the purposes of patent law is to protect innovation, and the directive has been set up with the purpose of protecting and furthering biotechnology investments while at the same time ensuring that both EU trade and the European Common Market operate in a way that enables European companies to compete with, for example, their American and Japanese counterparts.[58] In a Communication adopted by the Commission in 2002, it is pointed out that, in view of the rapid scientific progress in the fields of life sciences and biotechnology, close attention must be paid to legislation on intellectual property.[59] Hence regular review of whether the patent system is meeting European needs can now be expected.

The Biotechnology directive sets out requirements determining when an invention can be patented, but it does not control the utilisation of inventions. Such utilisation is a decision for the national authorities, considering health, safety and environmental concerns. Equally, there may be other laws prohibiting the production or use of a biotechnological invention. The legal basis of both the directive – and indeed the fundamental principle of protection – is that discoveries, in contrast with inventions, are not patentable.[60]

The Biotechnology directive does provide some clarification on the patentability of inventions involving animals. It reiterates that plants are patentable, but that plant varieties – which can be legally determined – are not. When it comes to animals, there is no legal definition of an animal variety. Animal varieties are not patentable but inventions relating to animals are patentable if the technical feasibility of the invention is not confined to a particular animal variety. This has important implications for genetically modified animals. Genes are not patentable as such, but only in connection with a particular inventive step and a proven

[55] The Dutch Government filed a nullity suit at the European Court of Justice against the directive based on a number of reasons, among them, the fact that it violates the basic rights of citizens. The Italian Government joined the opposition by recognising that many people may find patents on living organisms morally unacceptable, thus promoting the view that life is a mere commodity.

[56] Report from the Commission to the European Parliament and the Council. Development and implications of patent law in the field of biotechnology and genetic engineering. Brussels, 07.10.2002.

[57] In the first 5-yearly report on whether the directive has raised any problems (2002), see previous note, it was pointed out that not all member states had transposed the directive into their natinal legal systems.

[58] Opinion on ethical questions arising from the Commission proposal for a Council directive on legal protection for biotechnological inventions. Opinion of the group of advisers on the ethical implications of biotechnology to the European Commission. 30.09.1993.

[59] Commission Communication "Life sciences and biotechnology – a strategy for Europe", 23.01.2002.

[60] In general, whether an invention is patentable relies on country specific criteria. Under the US system, for example, four requirements always have to be met: (1) pratical utility, (2) either a process or a physical embodiment of the invention, (3) not be disclosed, (4) not be obvious. In other, European countries, e.g. Denmark, six criteria apply: (1) invention and not just discovery, (2) (industrial) application, (3) Description and reproducablity, (4) worldwide novelty, (5) not be obvious, and (6) not be against *ordre* public or morality.

industrial application. The Administrative Council of the European Patent Office decided in 1999 that genetically modified plants and animals are patentable. It is worth noting that the directive explicitly extends the patentability of a process like cloning to all plant and animal varieties.

In the Biotechnology directive it is stated that human cloning cannot be subject matter of a patent. This limit reflects the wish of the European legislature to exclude inventions whose commercial exploitation would be contrary to public order and morality. However, no explicit mention of animal cloning is made in the directive. Since animal cloning is not explicitly included in the directive, the implication *could* be that animal cloning is patentable. Certainly, the patent authorities have previously accepted patents on GM animals such as Onco mouse. However, since the listing in the directive of non-patentable procedures and products is not exhaustive, it is possible that the patenting of a cloned animal would be considered contrary to public order and morality. And as a cloned animal is a copy of an existing animal, it could be difficult to fulfil the invention requirement (even if the techniques and procedures involved in the cloning are patentable).[61]

The very limited number of clones available in the EU, and the fact that no cloned animal products so far have entered the market, may explain the absence of any explicit mention of cloned animals in the directive.[62]

At any rate, since the adoption of the directive, several follow-up actions have been identified. The European Group on Life Sciences (EGLS) pointed out in 2000 that excessively broad patents may lead to dependency problems, and that there is a need for wider communication of the objectives of patent law and its potential socio-economic benefits to the scientist and the general public. But none of these follow-up meetings and activities has addressed the animal cloning issue in writing.[63]

To summarise, there are some uncertainties at both the international and EU level regarding the ownership and patentability of the basic processes of animal cloning through nuclear transfer, the patentability of the animals created thereby and the patentability of derived products. The Biotechnology directive (98/44/EC), while stating that human cloning cannot be subject matter of a patent, is silent about animal cloning. There is a non-exhaustive list of unpatentable processes which may suggest that animal cloning can be subject to patenting. However, since the listing, in the directive, of non-patentable procedures and products is not exhaustive, it is still possible that the patenting of a cloned animal would be considered contrary to *ordre public* and morality. In addition, the question remains whether the invention criterion is satisfied when it comes to cloned animals.

[61] See Laurie, G. 2003. Intellectual property protection of biotechnological inventions and related materials. Innogen working paper 4 for a discussion of this, and other biotech intellectual property right court cases.
[62] Galli, C., Duchi, R., Lagutina, Lazzari, G. 2004. A European perspective on animal cloning and government regulation. *IEEE Engineering in Medicine and Biology Magazine* March/April 2004, pp. 52-54.
[63] Report from the Commission to the European Parliament and the Council. Development and implications of patent law in the field of biotechnology and genetic engineering. Brussels, 07.10.2002.

6. Conclusions

The overall objective of this report has been to review the state of the existing regulatory framework governing farm animal cloning, and to report on the actual practice of animal biotechnology regulation, both nationally and at EU level. This review forms the basis of a second legal report containing a more thorough *assessment* of the legal framework currently in place. The report has focused on aspects of the legal framework with an impact on research into, and applications of, farm animal cloning.

Unlike the genetic modification of animals, cloning is not directly regulated at EU level. The only piece of EU legislation applying to cloned animals for food production is EU Regulation No 258/97 on novel foods and novel food ingredients *if* food derived from cloned animals is considered to fulfil the legal criteria stated in the Regulation. Only a few Member States have national legislation that covers the cloning of farm animals. As yet, no products from cloned animals or their offspring are on the market. However, there are a number of directives and Regulations addressing issues raised by animal cloning such as animal welfare, intellectual property protection, the use of GMOs and product labelling. The Novel Food Regulation (258/97) needs to be assessed as an instrument regulating food-related uses of cloning. The GM directive 2001/18/EC also needs to be evaluated for its relevance to animal cloning. Likewise, zootechnical and other animal health and welfare legislation should be checked for the potential existence of a legal vacuum (e.g. in relation to sperm transfer).

In most countries, no legislation directly prohibits the cloning of animals, including farm animals. To date, Denmark and Norway are the two only European countries to have passed specific legislation in the area of animal cloning. The Danish legislation covers all kinds of cloning, including cloning processes that take place in nature (embryo splitting). The Norwegian and Danish legislation only covers the production of cloned animals and does not address imports of cloned animals.

More and more animal cloning activity is reported to be taking place outside the EU. In particular, the US, Australia, New Zealand and several Asian countries including Japan, South Korea and China are making advances in farm animal species cloning. Like their European counterparts, the major research-heavy countries such as the US, Canada, Australia, China and Japan have no specific legislation on animal cloning. Thus in the US there is no legislation specifically designed to control the cloning of animals. The US, as a matter of course, regulates *products* and not processes (such as cloning). With regard to food, the EU is also regulating products. Japan is reported to have significant farm animal cloning activities; likewise South Korea and China. These countries will probably use cloning and allow sales of clone-derived products in their home markets. This will present a WTO challenge. Efforts by EU countries to prevent these products from entering the European common market, with the stated aim of protecting consumer interests, will probably depend on the WTO's interpretation of the precautionary principle, and on what the WTO sees as a "legitimate concern".

According to the Opinion of the Group of Advisers on Ethical Implications of Biotechnology to the European Commission – which is not legally binding – the cloning of farm animal species for research is acceptable only if it is carried out under conditions which avoid or minimise animal suffering. The reason for permitting animal cloning research is, according to

the Group, is that it is likely to add to our knowledge and understanding of biological processes. In the agricultural context, animal cloning was seen as a way to improve the selection of animals having specific qualities, either innate or acquired by genetic modification.

International legal instruments usually take the form of treaties or conventions. These form agreements between the independent states which sign and then ratify them. Worldwide trade agreements are handled by the WTO, which deals with the rules of trade between nations. The EU issues directives and Regulations which are legally binding on Member States. In the case of directives, Member States are obliged to implement the relevant content in national legislation. However, the speed and level of detail at which this is done varies between states.

The most binding form of regulatory mechanism at the national level is a statute or law which sets out permitted or prohibited activities with penalties for non-compliance, or requires action which promotes consumer protection and consumer choice through, for instance, product labelling. In addition, ministries may issue guidelines or codes that are not legally binding. Consumer interests and public protection can be met with labelling regulations. A more draconian option is to exclude cloned or cloned derived products from the markets.

The EU has adopted a scientific and risk-based approach to food. In law it will be necessary to differentiate, and then legislate, for the various food types derived from cloning technology. Pharmaceuticals (and cosmetics, and nutraceuticals etc.) derived from products derived from cloned animals will also have to be considered. If it is determined, in the interests of the public (e.g. out of respect for the right of individuals to choose the kinds of technology involved in food production), that traceability systems must be implemented for products derived from cloned animals within the food chain, then it will be necessary to identify and track every product/ingredient derived from a cloned animal from source to consumption.

With regard to patenting, there are unresolved legal issues at the international and EU level about the ownership and patentability of the basic process of producing cloned animals through nuclear transfer, the patentability of the animals created thereby, and the patentability of derived products. These issues have been considered by the courts and the patent office. They are issues for public discussion. The Biotechnology directive (98/44/EC), while stating that human cloning cannot be the subject matter of a patent, is silent on animal cloning. There is a non-exhaustive list of unpatentable processes. This may suggest that animal cloning is suitable for patenting. However, since the listing, in the directive, of non-patentable procedures and products is not exhaustive, it is still possible that patenting a cloned animal will be deemed contrary to *ordre public* and morality. In addition, the question remains whether the invention criteria are satisfied when it comes to cloned animals.

Below, some of the main questions and key issues identified in this report in relation to regulation of farm animal cloning are recapitulated:

Regulation of cloning activity

Before an activity is regulated, consideration needs to be given to its novelty and desirability; and a number of questions need to be asked:

- Does the activity raise any new ethical issues? If the answer is yes, these issues need to be discussed both at the expert advisory and public level.
- Does the activity involve any risks? Risks to, for example, animal welfare, or human or environmental safety, need to be identified and assessed.
- Does the activity fall under any existing regulation? A view needs to be taken as to whether the activity is controlled by existing regulations, or whether those regulations can be amended to deal with the activity more effectively.
- Is regulation required to deal specifically with this activity? It may be that existing regulations only deal with some aspects of the activity.
- What is the appropriate form of regulation?

Regulation and possible public concerns

Some of the public concerns to consider might include:

- Loss of genetic diversity – selecting certain attributes, may ignore advantages attaching to other breeding lines.
- Unknown complications – selectively breeding into animals genetic faults which will affect the food chain in future decades.
- Inbreeding of cloned breeding lines.
- The use of growth hormone or accelerated growth due to modification causing health problems particularly with children consumers.
- The "What's in it for me?" approach – it is necessary to show consumers (and not just shareholders) the benefits of cloning.
- Distribution of the costs of traceability within the industry; the burden of these costs could damage small producers.
- The potential for fraud is considerable if labelling is required regardless of detectability.

Regulation and free markets

Some of the main problems to consider in relation to products derived from cloned animals and free movement of goods will arise:

- Where products permitted in one member state are able to move freely within the Union.
- Where products are imported into Europe from Non-Member States (particularly the US) and Europe adopts a different approach from that of the main international producers.
- Where products permitted in Europe are exported to countries with different standards/requirements.

Regulation and patentability

Some of the key questions about intellectual property in modern biotechnology are:

- How can traditional principles of patentability be applied to new technologies?
- Can be property rights be granted over genes? Can the products of modern biotechnology be categorised as inventions, or are they mere discoveries (and thus not patentable)? European courts have questioned the ability of the patent system to accommodate modern biotechnological products.

- Which international conventions and treaties address biotechnology, and in particular animal cloning?
- Is there a European directive on modern biotechnology in place?
- Does patent law cover animal biotechnology and animal cloning?
- What steps have been taken to harmonise patent law when it comes to animal biotechnology?

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